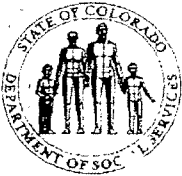


EXHIBIT 78



RICHARD D. LAMM
GOVERNOR

State of Colorado

DEPARTMENT OF SOCIAL SERVICES

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RUBEN A. VALDEZ
Executive Director

September 17, 1986

Health Care Financing Administration
Department of Health and Human Services
Attn: BERC-356-P
P.O. Box 26676
Baltimore, MD 21207

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REGULATIONS STAFF BPP
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Dear Sirs:

The proposed regulatory changes regarding drug reimbursement reform for Medicaid has been reviewed by my staff.

I agree that some changes should be made to improve drug reimbursement which would be advantageous to all participants in Title XIX. However, each proposed change as discussed in the Federal Register, Vol. 51, No. 160, raises some concerns in our minds.

Currently, Colorado has a state MAC program covering 231 dosage forms of multi-source drugs. We are continually reviewing drugs as their patents expire for potential cost controls. The process as it is being administered is acceptable to the pharmacy community.

Following are our comments on the three proposed changes.

1. Revision of the MAC Program

HCFA's assessment that the MAC program needs revision is correct. However, some of the solutions may cause smaller states some problems. The revision suggests that MAC levels be set by HCFA utilizing a rule of thumb that the subject drug be available through at least three suppliers, that it have a therapeutic rating of "A" by the FDA, and that the potential savings nationwide would be \$50,000.

There are problems still inherent in HCFA's plan to set the MAC prices at the federal level even though a survey of wholesalers is proposed as well as establishment of regional MAC's when necessary. These prices would be set more accurately and equitably if they were determined at the state level by the Single State Agency. At least half the states have already established a state MAC program which addresses local problems such as brands available within the state, volume of multi-source drugs dispensed, pricing practices of local wholesalers, etc. HCFA regulations should contain only general guidelines requiring states to establish MAC's and allow the value of each MAC to be set at the state level.

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It is crucial to monitor the availability of generic products in a local area when the single source brand loses its patent. Even though FDA may approve drugs to be produced and sold, some companies have difficulty meeting demand. Therefore, the drug may not be widely available for several months.

HCFA's nationwide figure of \$50,000 savings suggested as a minimum amount to trigger a MAC would translate into negligible savings in smaller states. By setting the MAC on such a drug, the administrative costs at the state level may outweigh the savings. In addition, pharmacies may not choose to stock a generic drug for so few prescriptions thereby making the drug unavailable to Medicaid recipients. A physician's solution to the problem caused by unavailability would be to prescribe higher cost single source drugs.

States are able to change their MAC's more quickly than the federal government, even under HCFA's proposed changes since there is one less layer of government to participate in the process.

2. PhIP Alternative

The PhIP plan may show savings in states where a state MAC program has not been implemented. However, in states where a state MAC does exist, PhIP could result in increased expenditures for generically equivalent drugs which are therapeutically substitutable. In Colorado, both the state and federal MAC's are considered ceiling prices for which generic drugs are reimbursed. If the drugs cost less than the MAC, then the state's maximum reimbursable level is the lesser figure. There is a pharmacy support in Colorado for this methodology.

Again, some of the companies selling generics which are listed in the Red Book or Blue Book are not available nationwide. If the PhIP price is set utilizing these sources, the availability in smaller states may be jeopardized. The problems inherent with levels set at the federal level on drugs with expiring patents are the same as those discussed under MAC.

3. CIP Alternative

Contrary to HCFA's assumption that the administrative costs for such a radical change in philosophy of payment will be small, we believe the costs will be substantial. Furthermore, it could not be implemented very quickly. The programming for payment is a major change in the MMIS as well as the switch in source of pricing information, i.e., drug reference file vs. profile table. In addition, the profiles would include many different unrelated business types, i.e., chain pharmacies in metropolitan areas vs. independent pharmacies in the rural area. If discounts are set too high, it may become unprofitable for rural pharmacies to participate thus creating areas in the state without providers.

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HCFA must look closely at the number of pharmacies who have a true usual and customary charge to the public and serve Medicaid clients in order to set screens. In Colorado, approximately 60% of the prescriptions billed to Medicaid are for nursing home patients. Most of these are provided by pharmacies who dispense drugs to nursing homes exclusively and their usual and customary charge is based upon the Medicaid allowable. In addition, there are parts of the state with a large Medicaid population which accounts for most of the area's health care dollars. These pharmacies also use the Medicaid allowable as their usual and customary. Therefore, there may be only 20-25% of the prescriptions from the rest of the pharmacies in the state from which true usual and customary charge data can be gathered.

An additional concern is the requirement that states would not be allowed to update screens less often than annually. This would result in some serious problems with availability and access to services for Medicaid recipients. Manufacturers do not raise their drug prices only once a year. They are constantly adjusting their charges. For a service where the reimbursement is largely paid to cover the cost of the ingredient, not being able to change profile screens on an as needed basis would result in payments to pharmacists which would not cover costs during part of the year. Therefore, pharmacists would refuse to accept the loss and make each of the drugs unavailable when presented with a Medicaid prescription. This situation would result in potentially more hospitalizations if a patient was unable to obtain medications used in controlling chronic diseases such as those found in the elderly or an acute disease, such as an infection, which is only treatable with expensive antibiotics. This would cost the Medicaid program much more. If pharmacies refused to provide and bill for the drugs because of inadequate reimbursement, very little data would be available to adjust the screen during the annual update.

Currently, there is enough competition to keep inflationary pressures from causing increases in prices in some areas. However, since the CIP design includes a government discount from the usual and customary charges, an incentive for inflation will already be present, particularly in those areas with a large Medicaid population. Usual and customary prices are set to meet operating costs as well as competition. Therefore, if the reduction in the reimbursement level causes a reduction in operating capital and threatens the business, either one of two actions must be taken: raise prices or close the business.

Screens in the payment system would help control any fraud or abuse. The current protections under MAC/EAC would not aid in fraud detection as much as it does under the current system. Protection from different kinds of fraud such as usual and customary creep would have to be designed.

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If CIP were to be implemented, it would be imperative to set any discount with provider input and negotiations. A discount amount cannot be suggested without a complete study of the process.

Published data in Red Book or Blue Book should be used with caution. Market surveys of various brands of generics should be used to verify accuracy of the data. The publications in the past have not conducted surveys but have accepted data submitted by manufacturers. They have begun to implement some changes in their approaches to accepting data. Submission of artificially high AWP prices has been used as a marketing tool by the generic companies to sell their products. In addition, price changes of many generic companies do not appear in the supplements of these publications.

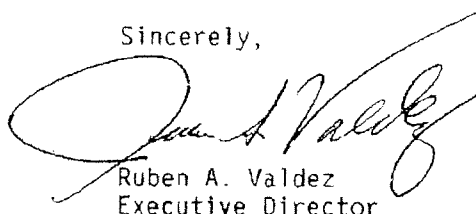
The regulations should not be changed just to address payment for traditional dispensing of drugs and their reimbursement. The services provided by home care specialty pharmacies should be incorporated into the regulatory definitions. Many provide home monitoring, teaching, etc., which have no connection with dispensing drugs but with the administration of the medication. They are not providing the same type of care as defined under home health. In order to continue providing care in the home rather than hospitals or nursing homes which results in savings for Medicaid, changes must be made to allow for payment for newer services.

In summary, a revised MAC reimbursement would cause fewer administrative problems for Colorado and would be preferred. The PhIP option would not cause any more administrative problems than MAC; however, under either of these options, the actual dollar figure of the limit should be set at the state level, not at the federal. In each of the proposed changes, an attempt was made to identify problems, etc., which may affect a particular state and waivers for certain situations were allowed. Rather than create a new set of requirements and work to obtain waivers so that the availability of drugs is present at the local level, states should be authorized to set prices.

CIP, as described, would take a great amount of reprogramming and administrative time. If recognition is not given to differences among all different types of pharmacies, then there will be areas of the state where services won't be available. Other pharmacies who provide more services than mass merchandisers may be forced to cut some services because of reduced payments.

If you have any questions, please do not hesitate to contact Myrle Myers, at (303) 294-2535.

Sincerely,



Ruben A. Valdez
Executive Director